TRANSDUCER SELECTION IN THE SPEED AND QUALITY OF IMAGE ACQUISITION IN FAST EXAMS

Study Protocol

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Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

Protocol Number: **H-46446**
Status: Approved
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Section Aa: Title & PI

A1. Main Title

TRANSDUCER SELECTION IN THE SPEED AND QUALITY OF IMAGE ACQUISITION IN FAST EXAMS

A2. Principal Investigator

Name:	SHERWIN SOLTANI	Phone:	
Id:	193744	Fax:	713 8736604
Department:	EMERGENCY MEDICINE	Email:	sherwin.soltani@bcm.edu
Center:		Mail Stn:	BCM285

A3. Administrative Contact

Name:	FAISAL AL OBAIDE	Phone:	713 8735297
Id:	179629	Fax:	713 7987665
		Email:	obaide@bcm.edu
		Mail Stn:	BCM285

A3a. Financial Conflict of Interest

Does any member of study personnel (Investigator (including investigator's spouse and/or dependent children)) that are involved in the design, conduct, or reporting of the research have a Significant Financial Interest (SFI) that would reasonably appear to be affected by the research for which funding is sought and/or associated with an entity/business that would reasonably appear to be affected by the research?

No

Section Ab: General Information

A4. Co-Investigators

Name:	JENNIFER CARNELL	Phone:	713 8732626
Id:	172170	Fax:	713 8732325
Department:	EMERGENCY MEDICINE	Email:	carnell@bcm.edu
Center:		Mail Stn:	BCM285

Name:	KELLY KEENE	Phone:	713 8737042
Id:	179417	Fax:	713 8732325
Department:	EMERGENCY MEDICINE	Email:	keene@bcm.edu
Center:		Mail Stn:	BCM285

Name:	LAMEES ALSHAIKH	Phone:	
Id:	193728	Fax:	
Department:	EMERGENCY MEDICINE	Email:	lalshaik@bcm.edu
Center:		Mail Stn:	BCM285

Name:	KONRAD KARASEK	Phone:	713 7986415
Id:	208388	Fax:	713 8736604
Department:	EMERGENCY MEDICINE	Email:	karasek@bcm.edu
Center:		Mail Stn:	BCM285

Name:	IDEEN ZEINALI	Phone:	
Id:	231072	Fax:	
Department:	EMERGENCY MEDICINE	Email:	231072@bcm.edu
Center:		Mail Stn:	

A5. Funding Source:

Baylor College of Medicine (Internal Funding Only)

A6a. Institution(s) where work will be performed:

BCM: Baylor College of Medicine

A6b. Research conducted outside of the United States:

Country:
Facility/Institution:
Contact/Investigator:
Phone Number:

If documentation of assurances has not been sent to the Office of Research, please explain:

A7. Research Category:

A8. Therapeutic Intent

Does this trial have therapeutic intent?

No

A9. ClinicalTrails.gov Registration

Does this trial meet the definition of an Applicable Clinical Trial and require registration on ClinicalTrials.gov?

Yes

Who will be responsible for registering and maintaining the registration of this Applicable Clinical Trial?

The BCM PI will register the trial because either:

- the trial is BCM PI-initiated,
- BCM is the lead site of this multicenter trial, or,

- the industry sponsor has instructed the BCM PI to register the trial, or,
- registration of this trail is required as a term and condition of the reward by the funding agency.

ClinicalTrials.gov Identifier:
NCT

Section B: Exempt Request

B. Exempt From IRB Review

Not Applicable

Section C: Background Information

The Focused Assessment of Sonography for Trauma (FAST) is a rapid point-of-care ultrasound exam performed on blunt and penetrating trauma patients who are too critically injured to be transported to a CT scanner. In performing this exam, time to acquisition of adequate images is crucial to clinical decision-making as patients undergoing this exam have a high probability of deteriorating if not intervened on appropriately.

Low-frequency ultrasound is used to image the abdominal cavity in these patients, using either a curvilinear transducer (colloquially, an "abdominal probe") or a phased-array transducer (a "cardiac probe"). Both of these transducers are capable of acquiring the images necessary to interpret a FAST exam, but it has not been studied whether using one transducer instead of the other improves time to image acquisition or image quality.

Section D: Purpose and Objectives

This protocol will evaluate whether there is a difference in the speed or quality with which emergency medicine residents and medical students are able to acquire images for the FAST exam depending on the type of transducer (curvilinear or phased array) they use for the exam.

Section E: Protocol Risks/Subjects

E1. Risk Category

Category 1: Research not involving greater than minimum risk.

E2. Subjects

Gender:
Both

Age:
Adult (18-64 yrs)

Ethnicity:
All Ethnicities

Primary Language:
English

Groups to be recruited will include:

Healthy, non-patient, normals

Which if any of the following vulnerable populations will be recruited as subjects?

Employees or lab personnel, Women of child bearing potential

Vulnerable populations require special protections. How will you obtain informed consent, protect subject confidentiality, and prevent undue coercion?

Our population, which includes both subjects that will perform the exam and will have the exam performed on them, will include women of child bearing potential. However, abdominal and cardiac ultrasonography is generally recognized as safe, with no known long-term adverse health effects. We do not anticipate a negative effect of the performance of these ultrasound exams on the health of our subjects or their future child-bearing potential. Human model patients who are pregnant will be excluded from the study.

We will be recruiting residents and faculty in this study. Study participation and data will not affect participant evaluations or consideration of employment status and this will be reflected on the written informed consent. We will take measures to de-identify the study data and prevent future re-identification of the study data. We will not recruit individuals who have limited decision-making capacity.

E3. Pregnant woman/fetus

Will pregnant women and/or fetuses (as described in 45 CFR 46 Subpart B) be enrolled in the research?

No

E4. Neonates

Will neonates of uncertain viability or nonviable neonates (as described in 45 CFR 46 Subpart B) be enrolled in the research?

No

E5. Children

Will children be enrolled in the research?

No

Section F: Design/Procedure

F1. Design

Select one category that most adequately describes your research:

c) Pilot

Discuss the research design including but not limited to such issues as: probability of group assignment, potential for subject to be randomized to placebo group, use of control subjects, etc.

Participants will be block-randomized to a group A and group B. For the purposes of this text, the term "operators" will refer to the participants who are performing the ultrasound exam. The term "patients" will refer to the healthy volunteers with no medical conditions who will have the ultrasound exam performed on them.

Group A will conduct an ultrasound exam on one patient using a curvilinear transducer, and group B performs the exam on another different patient using a phased-array transducer. After each operator performs their examination, they will cross-over, performing the same exam using the other transducer on the other patient.

Inclusion Criteria:

Emergency medicine residents (PGY 1-3), emergency medicine PA fellows, and emergency medicine faculty at Baylor College of Medicine will be recruited as operators. Healthy, non-pregnant emergency medicine faculty members recruited from Baylor College of Medicine who sign a written informed consent to be the subjects of the ultrasound examination will be used as the model patients.

Exclusion Criteria:

Pregnant women, adults over age 64, individuals younger than 18, and any individuals who elect not to participate or who withdraw their consent at a later date.

F2. Procedure

The FAST exam is part of standard clinical care of the trauma patient and consists of four views of the thorax and abdomen acquired with an ultrasound transducer. These views are: subxiphoid images of the heart; right upper quadrant images of the hepato-renal recess and right paracolic gutter; left upper quadrant images of the spleen-diaphragm interface, spleno-renal recess, and left paracolic gutter; and suprapubic images of the bladder and recto-vesicular or recto-vaginal pouch. Each operator will perform two ultrasound exams each with a different type of ultrasound transducer. The performance of ultrasound exams is part of standard clinical training of emergency medicine practitioners and medical students, and is considered a procedure with minimal risk to both the operator and patient. No part of the actual ultrasound exam being performed that is described here is investigational; all parts of this exam, performed with either the phased array or curvilinear probe, are considered the current standard of care for unstable trauma patients.

Prior to the ultrasound procedure we will administer a pre-survey to each participant. This survey will assess their knowledge of the adequate views of the FAST exam, their level of experience with the use of curvilinear and phased array probes, and their general level of ultrasound experience.

Each patient will be fasted for three hours prior to the exam.

Operators randomized to group A will perform an ultrasound exam on a patient using a phased-array transducer, and operators randomized to group B will perform an exam on the other patient using a curvilinear transducer. Both exams will be a complete FAST exam and each of the four exam components will be timed. After each subject in each group completes their FAST exam, they will cross-over.

The time to complete image acquisition of each of the four parts of the FAST exam will be collected for each subject with each transducer. The ultrasound images acquired for each transducer and each view will also be evaluated to assess them for quality of the acquired images, which will be graded as either adequate (sufficient for interpretation in a real patient) or inadequate (insufficient for interpretation in a real patient).

Section G: Sample Size/Data Analysis

G1. Sample Size

How many subjects (or specimens, or charts) will be used in this study?

Local: 40 Worldwide: 40

Please indicate why you chose the sample size proposed:

This is a convenience sample of the number of expected residents, PA fellows, and faculty that we expect to participate.

G2. Data Analysis

Provide a description of your plan for data analysis. State the types of comparisons you plan (e.g. comparison of means, comparison of proportions, regressions, analysis of variance). Which is the PRIMARY comparison/analysis? How will the analyses proposed relate to the primary purposes of your study?

Time to completion of each part of the ultrasound exam, total time to completion of the ultrasound exam, and whether or not the ultrasound exam is adequate or inadequate is the dependent variable. The independent variable is the type of ultrasound transducer (curvilinear or phased array) used for the ultrasound exam. The mean values of the time to completion will be compared in this data analysis and analyzed for significance, and whether or not the exam was adequate or inadequate will be compared (through a Fisher's exact test) to determine if there is a significant difference between the curvilinear transducer and the phased array transducer groups.

The primary comparison/analysis is the time to exam completion. The secondary comparison/analysis is

whether or not the exam was adequate. This analysis will determine if the hypothesis of the study, that there is a significant difference in time to completion and adequacy of the ultrasound exam, is supported or refuted.

Section H: Potential Risks/Discomforts

H1. Potential Risks/Discomforts

Describe and assess any potential risks/discomforts; (physical, psychological, social, legal, or other) and assess the likelihood and seriousness of such risks:

This protocol does not include exposure to ionizing radiation.

There are several risks for discomfort.

For the operators (subjects performing the exam), discomforts are primarily related to a loss of confidentiality in their results: having their times to completion or adequacy of the exam revealed to third parties. The likelihood of these risks is small, as we will securely store identifying research data in accordance with BCM policies and we will not disclose or report any identifiable research data outside of the study investigators.

For the patients (healthy volunteers having exams performed on them), discomforts may be related to: mild discomfort from having the ultrasound transducer pressed against the body during the examination, and social discomfort as they will have to partially expose their abdomen to undergo the portions of the FAST exam. Additionally, there may be a discomfort related to loss of confidentiality about participating in the study, and there is a small risk of the discovery of an incidental finding in each model patient.

There is very little risk of long-term damage or pain caused by the pressing of the ultrasound transducer against the body. The likelihood of social discomfort from disrobing depends on the individual comfort level of the subject. We will inform subjects of this risk, take care to ensure that they are adequately covered with sheets and clothing during the exam to protect their bodily privacy, and ensure that they are comfortable voicing any concerns or stopping the exam if necessary. The risk of confidentiality loss is small as we will take measures to secure identifiable data. Finally, there is a risk of the discovery of an incidental finding in the healthy model patients (for example the discovery of a renal cyst or abnormal abdominal fluid collection). This risk is inherent to the performance of any ultrasound exam. It is difficult to predict if patients will have incidental findings if they are otherwise healthy. Any incidental findings that are noted on the ultrasound exam by the PIs will be confidentially shared with the patient and they will be counseled to follow up on these findings as soon as possible with their physician.

H2. Data and safety monitoring plan

Do the study activities impart greater than minimal risk to subjects?

No

H3. Coordination of information among sites for multi-site research

Is the BCM Principal Investigator acting as the SPONSOR-INVESTIGATOR for this multi-site research?

No or Not Applicable

Is BCM the COORDINATING CENTER for this multi-site research?

No or Not Applicable

Section I: Potential Benefits

Describe potential benefit(s) to be gained by the individual subject as a result of participating in the planned work.

There is no potential benefit to each individual subject from this study.

Describe potential benefit(s) to society of the planned work.

The potential benefit to society is determining whether the choice of ultrasound transducer during the performance of this common ultrasound exam affects its performance or time to completion.

Do anticipated benefits outweigh potential risks? Discuss the risk-to-benefit ratio.

The anticipated benefits to society outweigh the risks to the subjects. There is no more than minimal risk to each individual subject related to the performance of a non-invasive ultrasound exam.

Section J: Consent Procedures

J1. Waiver of Consent

Will any portion of this research require a waiver of consent and authorization?

No

J1a. Waiver of requirement for written documentation of Consent

Will this research require a waiver of the requirement for written documentation of informed consent?

No

J2. Consent Procedures

Who will recruit subjects for this study?

PI

PI's staff

Describe how research population will be identified, recruitment procedures, any waiting period between informing the prospective participant and obtaining consent, steps taken to minimize the possibility of coercion or undue influence and consent procedures in detail.

The research population will be identified by using email and verbal solicitation to solicit participants in the study from BCM emergency medicine residents, PA/NP fellows, and emergency medicine faculty members. Subjects that will be used as the model patients will be identified by verbal and electronic solicitation to the faculty members of the Emergency Medicine Department at Baylor College of Medicine. It will be made clear that participation in the study is voluntary and will not affect grading, assessment, or employment status of any participant.

Are foreign language consent forms required for this protocol?

No

J3. Privacy and Intrusiveness

Will the research involve observation or intrusion in situations where the subjects would normally have an expectation of privacy?

No

J4. Children

Will children be enrolled in the research?

No

J5. Neonates

Will non-viable neonates or neonates of uncertain viability be involved in research?

No

J6. Consent Capacity - Adults who lack capacity

Will Adult subjects who lack the capacity to give informed consent be enrolled in the research?

No

J7. Prisoners

Will Prisoners be enrolled in the research?
No

Section K: Research Related Health Information and Confidentiality

Will research data include identifiable subject information?
Yes

Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.
No

Specific information concerning alcohol abuse:
No

Specific information concerning drug abuse:
No

Specific information concerning sickle cell anemia:
No

Specific information concerning HIV:
No

Specific information concerning psychiatry notes:
No

Demographic information (name, D.O.B., age, gender, race, etc.):
Yes

Full Social Security #:
No

Partial Social Security # (Last four digits):
No

Billing or financial records:
No

Photographs, videotapes, and/or audiotapes of you:
No

Identifiable biospecimens
No

Other:
Yes, as described:
Ultrasound clips and images will be retained as part of this study.

At what institution will the physical research data be kept?
Physical research data will be kept in locked storage in the PI's office at Ben Taub Hospital.

How will such physical research data be secured?
We will keep them in locked containers in a locked office.

At what institution will the electronic research data be kept?
Baylor College of Medicine

Such electronic research data will be secured via BCM IT Services- provided secured network storage of electronic research data (Non-Portable devices only):

Yes

Such electronic research data will be secured via Other:

No

Will there be anyone besides the PI, the study staff, the IRB and the sponsor, who will have access to identifiable research data?

No

Please describe the methods of transmission of any research data (including PHI, sensitive, and non-sensitive data) to sponsors and/or collaborators.

Data will be transmitted using BCM email or BCM Box.

Will you obtain a Certificate of Confidentiality for this study?

No

Please further discuss any potential confidentiality issues related to this study.

Copies of ultrasound images and clips will use coded numbers to identify participants with the identification key stored separately on BCM IT storage only accessible to the study investigators. This is necessary to allow the collected data and ultrasound images to be associated with each participant for the data analysis. Without the separate key it will not be possible to re-identify study participants.

Section L: Cost/Payment

Delineate clinical procedures from research procedures. Will subject's insurance (or subject) be responsible for research related costs? If so state for which items subject's insurance (or subject) will be responsible (surgery, device, drugs, etc). If appropriate, discuss the availability of financial counseling.

We do not anticipate that the research subjects will incur any cost by participating in this study.

If subjects will be paid (money, gift certificates, coupons, etc.) to participate in this research project, please note the total dollar amount (or dollar value amount) and distribution plan (one payment, pro-rated payment, paid upon completion, etc) of the payment.

Dollar Amount:

0

Distribution Plan:

Section M: Genetics

How would you classify your genetic study?

Discuss the potential for psychological, social, and/or physical harm subsequent to participation in this research. Please discuss, considering the following areas: risks to privacy, confidentiality, insurability, employability, immigration status, paternity status, educational opportunities, or social stigma.

Will subjects be offered any type of genetic education or counseling, and if so, who will provide the education or counseling and under what conditions will it be provided? If there is the possibility that a family's pedigree will be presented or published, please describe how you will protect family member's confidentiality?

Section N: Sample Collection

None

Section O: Drug Studies

Does the research involve the use of ANY drug* or biologic? (*A drug is defined as any substance that is used to elicit a pharmacologic or physiologic response whether it is for treatment or diagnostic purposes)

No

Does the research involve the use of ANY gene transfer agent for human gene transfer research?

No

O1. Current Drugs

Is this study placebo-controlled?

No

Will the research involve a radioactive drug?

No

Section P: Device Studies

Does this research study involve the use of ANY device?

Yes

Device 1: Sonosite X-Porte

Device 2: Sonosite Edge II

Device 3: Sonosite M-Turbo

Section Q: Consent Form(s)

Ultrasound transducer selection comparison in the FAST exam

Ultrasound transducer selection in the FAST exam - Healthy normal volunteer

Section R: Advertisements

None